

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 3-7 and 10 presently appear in this application and define patentable subject matter warranting their allowance.

Reconsideration and allowance are hereby respectfully solicited.

Claim 9 has been objected to by the examiner. This objection is made moot by the cancellation of claim 9 without prejudice.

Claim 2 and 10 have been rejected as containing new matter under 35 U.S.C. §112, first paragraph. This rejection is obviated by the cancellation of claim 2 and the amendment of claim 10 without prejudice.

Claims 5 and 6 have been rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The examiner states that the limitation of "said DNA does not consist of nucleotide residues 35 to 485 of SEQ ID NO:32" is new matter. However, the specification discloses at page 6, lines 13-16:

A DNA of human origin encoding the IL-18-binding protein of this invention usually

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comprises a part or the whole of the
nucleotide sequence shown in SEQ ID NO:32.
(emphasis is added)

Applicants believe that this recitation contains DNA consisting of nucleotide residues 35 to 485 of SEQ ID NO:32, which is excluded from claim 5. Applicant are excluding this DNA from claim 5 to avoid Adams et al. for locus AA311795, cited and applied by the examiner during prosecution. The exclusion of this DNA from claim 5 was made only to distinguish the claimed invention from the cited prior art which had not been expected by the applicant at the time the present application was filed. Applicants therefore believe that such an exclusion as recited in claims does not contain new matter and should be permitted.

With regard to claim 6, it should be noted that the specification discloses at page 6, IL-18-binding protein of human origin (having nucleotide sequence as shown in SEQ ID NO:1 and amino acid sequence as shown in SEQ ID NO:32) and its variants, as well as IL-18-binding protein of mouse origin (having nucleotide sequence as shown in SEQ ID NO:2 and amino acid sequence as shown in SEQ ID NO:33) and its variants. The specification in the paragraph bridging pages 37 and 38 further discloses that the human IL-18-binding protein has 61% amino acid sequence homology with the mouse IL-18-binding protein. Claim 6 claims a DNA which encodes IL-18-binding protein of human origin or the variants that are closer to human than mouse only among

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the IL-18-binding proteins of human and mouse origin and variants thereof.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-9 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is believed to be obviated by the amendments to the claims.

Claims 2, 5, and 6 remain rejected under 35 U.S.C. §112, first paragraph, for lack of enablement and for lack of written description. These rejections are respectfully traversed.

Claim 2 is now cancelled without prejudice, thereby obviating the rejections insofar as claim 2 is concerned.

With regard to claims 5 and 6, Experiment 1-3 at pages 18-19 of the specification discloses the digestion of the IL-18-binding protein with trypsin for peptide mapping. Some fragments of SEQ ID NO:1 are actually obtained in Experiment 1-3.

On the other hand, enzymatic digestion technique for fragmenting a polypeptide had been well known to a skilled person in the art at the time the present invention was made. Various enzymes, other than trypsin, such as subtilisin, ribonuclease, aminopeptidase, etc., had been well known to a skilled person in the art. Thus, it would have been easy for a person skilled in the art to obtain various fragments of the polypeptide having an

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amino acid sequence of SEQ ID NO:1 utilizing various enzymes and to determine the nucleotide sequences encoding the fragments, once the amino acid sequence of SEQ ID NO:1 and the example of trypsin digestion are given.

Furthermore, the specification discloses at page 19, Example 1-4, the method for screening the polypeptide fragment(s) of the present invention. According to the disclosure, it can be understood that the polypeptide fragment(s) of the present invention can be easily screened out from various fragments by testing their effect on the induction of IFN- γ production by human IL-18 in a system where the fragment(s) and human IL-18 coexist.

On the issue of lack of written description, applicants' comments presented above for the new matter rejection of claims 5 and 6 are applicable.

Reconsideration and withdrawal of the rejections are therefore respectfully requested.

Claims 1-4 and 7-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Adams et al. for locus AA311795 and further in view of Sibson et al. WO 94/015448 for the reasons set forth in the last Office Action, paper no. 12, at page 8. This rejection is respectfully traversed.

Applicants believe that because Adam's nucleotide sequence is now excluded from claims 1-4 as amended, it would not

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have been obvious for one of ordinary skill in the art to arrive at the presently claimed invention because Sibson merely discloses the desirability of generally placing a cDNA sequence into an expression vector and host cell to express the encoded protein. Claim 7 depends from claim 1 and therefore is patentable for the same reasons.

Reconsideration and withdrawal of the rejections are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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